R E M A R K S

This paper is responsive to an *Official Action* that issued in this case on September 17, 2008. In that *Action*, the Examiner found as follows:

- The disclosure was found to be objectionable because, as originally filed, it allegedly failed in the written description to "include where the receiver has not offset degrees of freedom and where the axes of all of said plurality degrees of freedom of said receiver intersect one another.
- Claims 1-15, 17-23, 34, and 36 were rejected under 35 USC §102 as being anticipated by U.S. Pat. No. 6,705,871 to Bevirt *et al*.
- Claims 16, 24, and 26-33 were rejected under 35 USC §103 as being obvious over U.S. Pat. No. 6,705,871 to Bevirt *et al*.

By this Amendment, claims 1, 10, 19, 24, 31, and 32 have been amended and claims 26-30, 33-34, and 36 have been canceled. Reconsideration is requested in view of the foregoing amendments and the following comments.

Objections to the Disclosure

Section 112 outlines three disclosure requirements that the inventor must comply with: (1) *the written description requirement*— the inventor must adequately describe the invention; (2) *the enablement requirement*— the inventor must describe the manner and process of making and using the invention; and, (3) *the best mode requirement*— the inventor must describe the best mode contemplated by the inventor for carrying out his or her invention.

The first paragraph of section 112 states that "[t]he specification shall contain a *written description* of the invention . . . ." The written description requirement ensures that the applicant had in his or her possession, as of the filing date of the application, the specific subject matter claimed by the applicant. As a consequence of its primary purpose, the written description requirement allows subsequent inventors to develop and obtain patent protection for later improvements and subservient inventions that build on the original applicant's invention.

It is clear that the present inventor did have "possession" of the concepts of "the receiver not having offset degrees of freedom" and "the axes of the degrees of freedom of the receiver intercepting another" at the time of filing. The "Background" section of applicant's specification discloses that having an offset degree of freedom is a drawback of the prior art (*see*, para. [0007]). It is further apparent to one skilled in the art from Figs 10A, 10B, and

10C that axes 1-1, 2-2, 3-3 of the degrees of freedom do indeed intersect. Furthermore, originally-filed claim 1 recited, in pertinent part that "said receiver has at least three degrees of freedom, wherein axes of said three degrees of freedom intersect." Also, originally-filed claim 24 recited, in pertinent part that "said receiver has no offset degrees of freedom."

The applicant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement. In other words, the precise wording of the claims need not appear in the written description. According to the Patent and Trademark Office Board of Patent Appeals and Interferences in *Ex parte Sorenson*, 3 U.S.P.Q.2d 1462, 1463 (P.T.O. Bd. Pat. App. & Int'f 1987), the test for determining whether a claimed invention is adequately described in the specification is whether the originally filed disclosure *reasonably* conveys to a person having ordinary skill in the art that the applicant had possession of the subject matter later claimed.

As demonstrated above, applicant's disclosure *reasonably* conveys to a person having ordinary skill in the art that the applicant had possession of the claimed subject matter. As a consequence, applicant urges the Examiner to withdraw the objection to the specification.

Art Rejections

The Examiner relies on a single reference, U.S. Pat. No. 6,705,871 ("the '871 patent"), to reject all pending claims. This reference, which discloses an interface mechanism for a computer simulation, provides some of the functionality as applicant's claimed invention. But it does so with a structure that is different from applicant's claimed invention. A few of the differences that are particularly relevant to the applicant's claimed invention are described below.

- In the device disclosed in the '871 patent, the end effector is pre-inserted into the mechanical interface apparatus (25) prior to beginning a simulation.
- In the device disclosed in the '871 patent, the intersection point of the various axes corresponding to the degrees of freedom intersect at a "remote" pivot point (P).

Regarding the first point, applicant's specification points to the fact that a shortcoming of the prior art is that the end effector (*i.e.*, the catheter unit assembly) is permanently coupled to the force-feedback system. Although not atypical for this type of system (*i.e.*, haptics devices) due to the difficulty of de-coupling an end effector from its force-feedback

system, this is very undesirable because to truly mimic most "actual" systems, de-coupling is necessary.

In the case of an actual vascular-access procedure, a medical practitioner experiences "force-feedback" during insertion of a needle or catheter (*i.e.*, an end effector) into a patient's arm. That is, the anatomy of the arm presents a resistance that is sensed (feedback) by the practitioner. In the actual procedure, the needle or catheter is not, of course, "coupled" to the arm *until* it is inserted by the practitioner. And that is when resistance is felt. And this is the way that applicant's claimed apparatus works – the needle-catheter assembly is separate from the force-feedback system (*e.g.*, the receiver) until the needle-catheter is inserted through the "pseudo skin" to begin the simulation.

But in the prior art that is discussed in applicant's specification, as well as in the '871 patent, the end effector (*i.e.*, user object (44)) is inserted prior to actually beginning the simulation. Although this is not made particularly clear in the '871 patent, it is clear upon close reading that such pre-insertion is required.

For example, consider the following passage at col. 6, line 55+, which describes simulating inserting the needle into the skin:

> The shaft portion (28) extends to mechanical apparatus 25, which provides the mechanical support, degrees of freedom, and force simulation for needle 18 that realistically simulates an epidural anesthesia or other procedure. For example, the needle 18 can preferably move in a linear degree of freedom to simulate inserting the needle in the skin…."

As indicated above, the shaft portion (28) of the needle (18) is coupled to the apparatus (*see* FIG. 3). To simulate insertion of the needle into the skin, the needle is then moved linearly forward.

Consider the following passage at col. 21, lines 10-25 that describes the use of apparatus to practice an epidural anesthesia procedure:

> When training an anesthesiologist using the simulator of the present invention, the trainee will typically practice the initial stages of the procedure on a patient or other conventional testing means, i.e., the trainee learns from an instructor how to place the patient on the operating table and locate the point of insertion about halfway between the vertebrae L4 and L5. At this point, the trainee can

> move over to the mechanical apparatus 25' and practice the remainder of the procedure.
>
> When operating the mechanical interface apparatus 25', the trainee aims the needle 18 approximately 10° toward the head of the patient (which can be displayed on a computer monitor or head mounted display). When appropriate needle position is attained, needle insertion is begun. Various forces are provided on the needle as it is inserted depending on the distance and direction of travel through simulated tissue, as explained below.

Note that the passage indicates that "when appropriate needle position is attained, needle insertion is begun." In this device, the only way it can be determined if the "appropriate needle position" is attained is if the needle is already engaged to needle mount (91), as per FIG. 3 of the '871 patent.

Consider also the following passage at col. 22, line 1 through col. 23, line 9 that describes the forces experienced upon simulated penetration of the skin:

> FIG. 8b is a graph 230 showing the force output on needle 18 using a physical property profile with respect to needle insertion depth for a desired (successful) trajectory of the needle in the simulated tissue of a patient. These forces result from a profile selected when the needle is advancing into the simulated tissue. Between and insertion depth of 0 and 0.5 inches, an initial force spike 232 is output in the direction resisting the advance of the needle, after which the force drops sharply. Spike 232 is intended to simulate the puncturing of skin by the tip of the needle shaft 28, and thus a high stiffness value (and/or other values) are stored in the profile for this insertion depth.

Referring to FIG. 1, device (25) is on one side of "skin" or other barrier (22) and the syringe (18) is on the other side. (*See*, *e.g.*, col. 6, line 66 through col. 7, line 1.) As a consequence, the "skin" would have to be "punctured" for the needle to couple to device (25). But as indicated above and in FIG. 8B, the needle is advanced as much as about 5/10 of an inch before a simulated puncture of the skin occurs at (232). This means that the needle engages device (25) before the simulation begins. Then the needle is advanced and, at some point, is considered to have penetrated the skin.

The disclosure is consistent: the simulation begins after the needle engages the device (25).

Regarding the second point, the '871 patent makes much of the fact that "the interface apparatus … provides a unique gimbal mechanism having a remote pivot point that allows a user manipulatable object to be positioned on one side of the pivot point and the gimbal mechanism entirely on the other side of the pivot point." (Col. 4, line 66 through col. 5, line 5.) The specification provides further detail about this at col. 8, lines 42+ disclosing that:

> The axes of rotation are arranged such that they intersect about a remote pivot point P, which is the center of the "sphere" defined by the gimbal mechanism 38. Pivot point P is "remote" in the sense that it is not positioned at (or touching) any member or coupling of the gimbal mechanism 38, but is positioned in free space away from the mechanism 38 and in another "hemisphere," as explained below.

This approach is markedly different than applicant's approach from positioning a user-manipulatable object on one side of a barrier (*e.g.*, skin, *etc.*), and a feedback mechanism on the other side. In applicant's claimed invention, the axes of rotation do NOT intersect about a remote pivot point. Rather, the intersection point falls just behind insertion point (1089), between frame (1149) of receiving module (1076) where axis 1-1 and axis 2-2 cross. (*See*, FIGs. 10C, 11A, *etc.*) Applicant is therefore able to achieve the same "separation" between a manipulatable object (*i.e.*, needle/catheter module 218) and a feedback mechanism (*i.e.*, needle-stick module 226), as depicted in FIGs. 4A and 4B of the drawings, but with a non-remote pivot point.

All independent claims of the application include at least one of the features discussed above that is not disclosed or otherwise suggested by the '871 patent.

Independent Claims 1 and 19

Amended claim 1 recites an apparatus comprising a receiver, wherein:

> said receiver has three degrees of freedom that enable said receiver to move in three different ways about three different axes, wherein axes of said three degrees of freedom intersect **at a point that is located within the receiver**; and
>
> said receiver receives an end effector, wherein said end effector removably couples to said receiver.

The '871 patent does not disclose what is recited in claim 1. In particular, the cited art does not disclose a receiver that has three degrees of freedom, wherein the axes of those degrees of freedom intersect at a point that is located within the receiver.

As a consequence, claim 1 is allowable over the '871 patent. Claims 2-18, which are dependent on claim 1, are allowable on that basis. The recitation of additional patentable features in dependent claims 2-18 provides a secondary basis for patentability.

Amended claim 19 recites an apparatus comprising a receiver for an end effector, wherein said receiver comprises:

> a frame;
>
> an arrangement for providing two orthogonal axes of rotation for said frame, wherein said frame is coupled to said arrangement; and
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> a movable member, wherein:
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> said movable member receives an end effector during a vascular access procedure;
>
> said movable member moves along a linear path in a region defined by said frame; and
>
> said linear path intersects said two orthogonal axes of rotation of said frame **at a point that is positioned in said frame**.

The '871 patent does not disclose what is recited in claim 19. In particular, the cited art does not disclose a movable member that moves along a linear path and the linear path intersects two orthogonal axes of rotation at a point that is positioned in said frame.

As a consequence, claim 19 is allowable over the '871 patent. Claims 20-24 and 31-32, which are dependent on claim 19, are allowable on that basis. The recitation of additional patentable features in these dependent claims provides a secondary basis for their patentability.

Conclusion

In view of the foregoing, it is believed that claims 1-24 and 31-32 now presented for examination are allowable over the art of record. A notice to that effect is therefore solicited.

Respectfully,
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